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(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Makoto ISHIKAWA et al.

Application No.: 10/518,926 Confirmation No.: 7260

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For: OIL-IN-WATER EMULSION COMPOSITION Examiner: Kugel, Timothy J.

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Madam:

I, Makoto ISHIKAWA, residing in Mie, Japan, hereby declares and states as follows:

1. That I am one of the co-inventors of U.S. Application Serial No. 10/518,926 filed on December 23, 2004, entitled OIL-IN-WATER EMULSION COMPOSITION. I am thoroughly familiar with the contents of said Application, its prosecution before the United States Patent and Trademark Office and the references cited therein.

2. That I am a graduate of University of the Ryukyus, Faculty of Agriculture and received a master's degree in the year 1994, majoring in bioscience and biotechnology.

3. That I have been employed in Taiyo Kagaku Co., Ltd. since 1994 and have been assigned to the Research Laboratories.

4. That I have been involved in the research and development of emulsified functional oils and fats formulation since 1999.

5. That the following statements were made to verify the difference between JP07-115901 (Kazuyoshi) using monoester emulsifiers and the present invention using diester emulsifiers.

EXPERIMENTAL METHODS

Preparation of Product A According to Example 1 of the Present Invention

An oil-in-water droplet emulsion composition was prepared in accordance with the method described in Example 1 of the present specification.

Specifically, in order to prepare a lipophilic preparation liquid, 120 g of sucrose fatty acid ester (sucrose acetate isobutyrate, manufactured by Eastman Chemical, HLB: 1) and 30 g of a vegetable oil [trade name: M-6, manufactured by Taiyo Kagaku Co., Ltd.] were warmed and melted, and 280 g of 22% DHA-containing purified fish oil [manufactured by K.K. Maruha] was added thereto, and the mixture was sufficiently mixed.

Next, in order to prepare a hydrophilic preparation liquid, 320 g of glycerol [manufactured by NOF Corporation], 30 g of pentaglycerol dimyristate [manufactured by Taiyo Kagaku Co., Ltd.] and 30 g of pentaglycerol dioleate [manufactured by Taiyo

Kagaku Co., Ltd.] were warmed and melted, and the mixture was sufficiently mixed. After the temperature was adjusted so that the temperature of the resulting mixture falls between 45° to 55°C, 180 g of ion-exchanged water was added thereto, and the mixture was further mixed.

The lipophilic preparation liquid obtained as mentioned above was gradually supplied into the hydrophilic preparation liquid as obtained above, and pre-emulsified with a Homo Mixer at 12000 rpm for about 10 minutes. The pre-emulsified mixture was allowed to pass through an emulsifier set to have a pressure of 1.47×10^7 Pa ($150\ kgf/cm^2$). As a result, about 950 g of an emulsion having an average particle size of from 0.2 to 0.8 μm was obtained. This emulsion was named Product A.

Preparation of Comparative Product B

An oil-in-water droplet emulsion composition was prepared in the same manner as in the method described in Example 1 of the present invention except for using a monoester as an emulsifier.

Specifically, in order to prepare a lipophilic preparation liquid, 120 g of sucrose fatty acid ester (sucrose acetate isobutyrate, manufactured by Eastman Chemical, HLB: 1) and 30 g of a vegetable oil [trade name: M-6, manufactured by Taiyo Kagaku Co., Ltd.] were warmed and melted, and 280 g of 22% DHA-containing purified fish oil [manufactured by K.K. Maruha] was added thereto, and the mixture was sufficiently mixed.

Next, in order to prepare a hydrophilic preparation liquid, 320 g of glycerol [manufactured by NOF Corporation], 30 g of pentaglycerol monomyristate [manufactured by Taiyo Kagaku Co., Ltd.] and 30 g of pentaglycerol monooleate

[manufactured by Taiyo Kagaku Co., Ltd.] were warmed and melted, and the mixture was sufficiently mixed. After the temperature was adjusted so that the temperature of the resulting mixture falls between 45° to 55°C, 180 g of ion-exchanged water was added thereto, and the mixture was further mixed.

The lipophilic preparation liquid obtained as mentioned above was gradually supplied into the hydrophilic preparation liquid as obtained above, and pre-emulsified with a Homo Mixer at 12000 rpm for about 10 minutes. The pre-emulsified mixture was allowed to pass through an emulsifier set to have a pressure of 1.47×10^7 Pa ($150\ kgf/cm^2$). As a result, about 950 g of an emulsion having an average particle size of from 0.2 to 0.8 μm was obtained. This emulsion was named Comparative Product B.

Preparation of Comparative Product C

An oil-in-water droplet emulsion composition was prepared in the same manner as in the method described in Example 1 of the present invention except for using decaglycerol monooleate used in Kazuyoshi as an emulsifier.

Specifically, in order to prepare a lipophilic preparation liquid, 120 g of sucrose fatty acid ester (sucrose acetate isobutyrate, manufactured by Eastman Chemical, HLB: 1) and 30 g of a vegetable oil [trade name: M-6, manufactured by Taiyo Kagaku Co., Ltd.] were warmed and melted, and 280 g of 22% DHA-containing purified fish oil [manufactured by K.K. Maruha] was added thereto, and the mixture was sufficiently mixed.

Next, in order to prepare a hydrophilic preparation liquid, 320 g of glycerol [manufactured by NOF Corporation], 60 g of decaglycerol monooleate [manufactured by Taiyo Kagaku Co., Ltd.] was warmed and melted, and the mixture was sufficiently mixed.

After the temperature was adjusted so that the temperature of the resulting mixture falls between 45° to 55°C, 180 g of ion-exchanged water was added thereto, and the mixture was further mixed.

The lipophilic preparation liquid obtained as mentioned above was gradually supplied into the hydrophilic preparation liquid as obtained above, and pre-emulsified with a Homo Mixer at 12000 rpm for about 10 minutes. The pre-emulsified mixture was allowed to pass through an emulsifier set to have a pressure of 1.47×10^7 Pa ($150\ kgf/cm^2$). As a result, about 950 g of an emulsion having an average particle size of from 0.2 to 0.8 μm was obtained. This emulsion was named Comparative Product C.

Test Example I

Test Example I was carried out in the same manner as in Test Example 1 of the present specification.

Specifically, 50 g of each of the compositions of Product A and Comparative Products B and C was added to 950 g of a commercially available cow's milk having milk fat of 3.5%, and the mixture was homogeneously mixed. The resulting mixture was warmed to 50°C and then cooled to 4°C, and a sensory test was conducted by 10 panelists. As a result, the taste of cow's milk with Product A was excellent, which was completely the same as the commercially available cow's milk. The results are shown in Table I.

Test Example II

Test Example II was carried out in the same manner as in Test Example 5 of the present specification.

Specifically, 50 g of each of the compositions of Product A and Comparative Products B and C was added to 950 g of a commercially available yogurt drink, and the mixture was homogeneously mixed. The resulting mixture was warmed to 50°C and then cooled to 4°C, and a sensory test was conducted by 10 panelists. As a result, the taste of yogurt drink with Product A was excellent, which was completely the same as the commercially available yogurt drink. The results are shown in Table I.

Test Example III

Test Example III was carried out in the same manner as in Test Example 9 of the present specification.

Specifically, 50 g of each of the compositions of Product A and Comparative Products B and C was added to 950 g of a commercially available orally taken liquid food, and the mixture was homogeneously mixed. The resulting mixture was warmed to 40°C and then cooled to 4°C, and a sensory test was conducted by 10 panelists. As a result, the taste of the orally taken liquid food with Product A was excellent, which was completely the same as the commercially available orally taken liquid food. The results are shown in Table I.

RESULTS

The taste was evaluated by showing the number of individuals who judged that the taste is marked different from a commercially available beverage out of the 10 panelists. The smaller the number of individuals, the better the taste.

Table I

	Test Ex. I Cow's Milk	Test Ex. II Yogurt Drink	Test Ex. III Orally Taken Liquid Food
Product A	1	1	0
Comparative Product B	3	2	3
Comparative Product C	3	3	3

As shown in Table I, it was found that the mixture containing Product A does not lose its taste by heating the mixture, and as a result, the taste is in the same level as a commercially available beverage. On the other hand, the mixtures containing Comparative Products A and B were found to show a change in taste due to heating.

DISCUSSION

It is clear from the results of Table I that in the experiment system of the present invention, the decaglycerol monooleate which is found to be effective in Kazuyoshi exhibits poorer effects as compared to those of the polyglycerol fatty acid ester of the present invention.

As a result of studying the causations therefor, it is considered that the use of a polyvalent unsaturated fatty acid in a larger amount than that in Kazuyoshi is one causation.

When the content of DHA is calculated regarding to this matter, while the present invention contains 0.3% DHA in food, Kazuyoshi contains 0.0024% DHA in the

foodstuff, so that it is made clear that the content of DHA in the present invention is 100 times or more concentrated than that of Kazuyoshi.

The reasons why there is such a difference in concentrations are presumably as follows. It is made clear that contrary to the teachings of Kazuyoshi, in a food containing a considerably large amount of a polyvalent unsaturated fatty acid as illustrated in Examples of the present specification, a monoester described in Kazuyoshi, which is not a specified polyglycerol fatty acid ester defined in the present invention, namely a diester or a triester, cannot exhibit sufficient effects, even if it is a polyglycerol fatty acid ester.

This is presumably due to the fact that the monoester is highly hydrophilic and contains a free hydroxyl group in a large amount, thereby making the thickness of the formed film on the oil droplet surface thinner, so that the formed film would not be as thick as that of the diester in the present invention.

Statement Under 18 U.S.C. § 1001

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: November 11, 2009 By

Makoto ISHIKAWA